09-02-03



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner

L. Helms

Group Art Unit

1615

:

Applicants

Bhami Shenoy et al.

Application No. : 10/034,950 Confirmation No.: 9344

For

Filed

December 26, 2001

CRYSTALS OF WHOLE ANTIBODIES AND

FRAGMENTS THEREOF AND METHODS FOR

MAKING AND USING THEM

New York, New York August 29, 2003

Hon. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is a Supplemental Information Disclosure Statement in the above-identified application.

This Statement is being submitted more than three months from the application filing date but before the mailing of a first Office Action on the merits under 37 C.F.R. §

1.97(b)(3), or a notice of allowance under 37 C.F.R. §

1.311, therefore it is timely without the payment of any additional fees.

The Director is hereby authorized to charge payment of any additional fees required in connection with the accompanying Supplemental Information Disclosure Statement, or credit any overpayment, to Deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.

Respect fully submitted,

Margaret A. Pierri (Reg. No. 30,709)

Attorney for Applicants

Andrew K. Holmes (Reg. No. 51,813)

Agent for Applicants

Customer No. 1473

c/o FISH & NEAVE

1251 Avenue of the Americas New York, New York 10020

Tel.: (212) 596-9000



TEH SER OF TOO SOO VPI/00-08

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner

: L. Helms

Group Art Unit

: 1615

Applicants

: Bhami Shenoy et al.

Application No. : 10/034,950 Confirmation No.: 9344

Filed

: December 26, 2001

For

: CRYSTALS OF WHOLE ANTIBODIES AND

FRAGMENTS THEREOF AND METHODS FOR MAKING

AND USING THEM

New York, New York August 29, 2003

Hon. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

> SUPPLEMENTAL STATEMENT UNDER 37 C.F.R. § 1.56 AND § 1.97(b)

Sir:

This Statement supplements applicants' Information Disclosure Statement, dated June 27, 2003.

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants, through their attorneys, make of record the following documents:

OTHER DOCUMENTS

Baselga et al., "Recombinant Humanized Anti-HER2 Antibody (Herceptin™) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin against HER2/neu Overexpressing Human Breast Cancer Xenografts," <u>Cancer Research</u>, Volume 58, pp. 2825-2831 (1998).

Brange et al., "Insulin Analogs With Improved Pharmacokinetic Profiles," <u>Advanced Drug Delivery Reviews</u>, Volume 35, pp. 307-335 (1999).

Colbern et al., "Antitumor Activity of Herceptin in Combination with STEALTH Liposomal Cisplatin or Nonliposomal in a HER2 Positive Human Breast Cancer Model," <u>Journal of Inorganic Biochemistry</u>, Volume 77, pp. 117-120 (1999).

Flieger et al., "Mechanism of Cytotoxicity Induced by Chimeric Mouse Human Monoclonal Antibody IDEC-C2B8 in CD-20-Expressing Lymphoma Cell Lines," Cellular Immunology, Volume 204, pp. 55-63 (2000).

Ghetie et al., "FcRn: the MHC Class I-related Receptor That is More Than an IgG Transporter," Immunology Today, Volume 18, pp. 592-598 (1997).

Hainsworth, "Rituximab as First-Line and Maintenance Therapy for Patients With Indolent Non-Hodgkin's Lymphoma: Interim Follow-Up of a Multicenter Phase II Trial," <u>Seminars in Oncology</u>, Volume 29, pp. 25-29 (2002).

Harris et al., "Comparison of Intact Antibody Structures and the Implications for Effector Function," Advances in Immunology, Volume 72, pp. 191-205 (1999).

Jen et al., "Diamonds in the Rough: Protein Crystals from a Formulation Perspective," <u>Pharmaceutical</u> <u>Research</u>, Volume 18, pp. 1483-1488 (2001).

Keating et al., "Infliximab, An Updated Review of its Use in Crohn's Disease and Rheumatoid Arthritis," Adis Drug Evaluation, Volume 16, pp. 111-148 (2002).

. 01

Kuznetsov et al., "Chimeric Human-Simian Anti-CD4 Antibodies form Crystalline High Symmetry Particles," <u>Journal of Structural Biology</u>, Volume 131, pp. 108-115 (2000).

Leyland-Jones et al., "Role of Herceptin® in Primary Breast Cancer: Views from North America and Europe," Oncology, Volume 61, pp. 83-91 (2001).

Ma et al., "Carbohydrate Analysis of a Chimeric Recombinant Monoclonal Antibody by Capillary Electrophoresis with Laser-Induced Fluorescence Detection," <u>Anal. Chem.</u>, Volume 71, pp. 5185-5192 (1999).

Applicants have attached a PTO-1449 Form listing these documents. Applicants request that these documents: (1) be fully considered by the Examiner during examination of this application and (2) be printed on any patent that may issue from this application. Applicants are submitting this Statement before the issuance of a first Office Action on the merits under 37 C.F.R. §1.97(b)(3).

The Director is hereby authorized to charge payment of any fees required in connection with this Supplemental Information Disclosure Statement to Deposit Account No. 06-1075.

A duplicate copy of the accompanying transmittal letter including that authorization is transmitted herewith.

Respectfully submitted

Margaret Pierri (Reg. No. 30,709)

Attorney for Applicants

Andrew K. Holmes (Reg. No. 51,813)

Agent for Applicants

Customer No. 1473

c/o FISH & NEAVE

1251 Avenue of the Americas

New York, New York 10020

Tel.: (212) 596-9000